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09/849,637	05/04/2001	Dov Malonek	20066.79	6911

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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 05/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/849,637

Applicant(s)

MALONEK ET AL.

Examiner

George R Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) 33,46-48 and 50-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 and 34-45 is/are rejected.
- 7) ☒ Claim(s) 49 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the election and restriction in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the searches for the respective groups will necessarily be co-extensive and searching all the groups will not be burdensome to the Examiner. This is not found persuasive because, as shown in the restriction, the groups are classified in different subclasses and the search is not co-extensive.

The requirement is still deemed proper and is therefore made FINAL.

Claims 33, 46-48, and 50-59 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Claim Objections

Claim 49 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must be in the alternative. See MPEP § 608.01(n). Accordingly, the claim 49 has not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-32, 34-40, 42, 44, and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In claim 2, "a signal characteristic" is vague since it has been used in claim 1. Is this the same signal characteristic as used in claim 1 or a different characteristic. It is suggested to use "said signal characteristic".

In claim 3, "a signal characteristic" and "a suitable...field" are vague.

In claim 6, "minimise" is misspelled.

Claims 7, 16, 28, and 31, comprise a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) and the claims are considered indefinite, since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). As an example, claim 7 recites the broad recitation of between 2mm to 10 mm, and the claim also recites preferably about 5 mm which is the narrower statement of the range/limitation.

In claim 8, "said distal portion" lacks antecedent basis.

In claims 12 and 19, the claims are improper Markush groupings. The suggested format for the claims are "are selected from the group consisting of:...". In addition, "or any other

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conductive material having suitable...characteristic” is vague since the claims or specification do not specifically point out what constitutes a “suitable” biostable and biocompatible characteristic.

In claim 13, “said distal portion” lacks antecedent basis.

In claim 14, “said external diameter” lacks antecedent basis.

In claim 24, “means of” is vague since it can not be determined if this is “means for” language using 35 USC 112, sixth paragraph; “said exposed surface” lacks antecedent basis. In addition, “joined...by means of a laser weld” is inferentially included and it is unclear if this is a positive recitation of a structural element or a functional recitation of a method step.

In claim 25, “means of” is vague and “connected by...means of crimping” is inferentially included. In addition, “a suitable well” is inferentially included and the claim has not set forth that the connector means has a “suitable well”.

In claim 26, “said flat terminal member” lacks antecedent basis.

In claim 29, “said distal portion” lacks antecedent basis and “via a length of suitable tubing” is inferentially included.

In claim 32, “said distal portion” lacks antecedent basis.

In claims 34-37, 40, 42, and 44, the claims are vague for limiting the control means or elements related to the control means. The “control means” has not been positively recited in any of the independent claims and has only been functionally recited (“for enabling...to be operatively connected to a suitable control means”). The applicant can either positively recite the control means or functionally recite the control means in regards to a positively recited element. The examiner has only considered the limitations of the control means as functional language since the control means has not been positively recited.

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In claims 38 and 39, "is used for" is vague since it is unclear if applicant is trying to claim a method step or an element to perform those functions.

In claim 45, "wherein said tissue is a human heart or part thereof" is vague since the applicant can not claim the human body. It is suggested to functionally recite the use of the lead, such as "wherein the tissue the lead is for modifying is the human heart...".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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Claims 1-7, 11, 20, and 34-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Ayers et al (5405375). Ayers is capable of meeting the functional use recitations presented in the claims.

Claims 1-8, 11, 12, 19, 20, 28, and 34-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Yang et al (5824030). Yang is capable of meeting the functional use recitations presented in the claims.

Claims 1-12, 19, 20, 32, 34-39, and 41-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Littmann et al (5957842). Littmann is capable of meeting the functional use recitations presented in the claims.

Claims 1-3, 11, 28-32, and 34-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Swoyer (5683445). Swoyer is capable of meeting the functional use recitations presented in the claims.

Claims 1-6, 11-13, 15-17, 19-21, 28, and 34-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Kroll et al. (Kroll is capable of meeting the functional use recitations presented in the claims.

Claims 1-7, 11-13, 15, 19, 21, 28, and 34-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Pless et al (5456706). Pless is capable of meeting the functional use recitations presented in the claims.

Claims 1-6, 11-13, 15, 19, 21, 28, and 34-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoffmann et al (5534022). Hoffmann is capable of meeting the functional use recitations presented in the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al (or Pless or Hoffmann). Kroll (or Pless or Hoffmann) discloses the claimed invention except for the diameter being less than 1.2 mm or the electrode impedance being between 50 and 500 Ohms. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead having electrodes as taught by Kroll (or Pless or Hoffmann), with the lead diameter being less than 1.2 mm and the electrode impedance being between 50 and 500 Ohms since it was known in the art that leads having electrodes use a lead diameter less than 1.2 mm to allow the lead to have a small footprint in the body and/or to allow the lead to be placed in the coronary veins and since it was known in the art that leads having

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electrodes provide the electrode with an impedance between about 50 to about 500 Ohms to provide a low impedance lead that will not waste energy of the implantable device.

Claims 22-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll (or Pless or Hoffman or Ayers or Yang or Littmann). Kroll (or Pless or Hoffman or Ayers or Yang or Littmann) discloses the claimed invention except for the multiple lumens each having a conductor (claim 22), the particulars of the distal connector means comprising a substantially flat terminal member (claim 23), connecting the conductors to the distal connector using laser welding or crimping (claims 24 and 25), the terminal member being titanium (claim 26), and spiraling of the conductors in the lead lumen (claim 27). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead having electrodes as taught by Kroll (or Pless or Hoffman or Ayers or Yang or Littmann), with the lead having multiple lumens with each lumen having a conductor, connection of the conductors to distal connectors using laser welding or crimping, and the spiral conductors in the lumens since it was known in the art that leads having electrodes use: multiple lumens, with each lumen having a conductor in the lumen to allow the lead body to have a smaller footprint in the body by not using insulation on each conductor; laser welding or crimping to connect conductors to distal connectors to provide a fast, secure method for the connection of different elements; and to spiral the conductor in the lumen to allow the lead to be more flexible and less resistant to breakage.

In addition, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the lead having electrodes as taught by Kroll (or Pless or Hoffman or Ayers or Yang or Littmann) with the particulars of the distal connector means comprising a flat terminal member and the terminal member being titanium, because Applicant

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has not disclosed that the particulars of the distal connector means comprising a flat terminal member and the terminal member being titanium provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the connections of the conductors to the connectors as taught by Kroll (or Pless or Hoffman or Ayers or Yang or Littmann), because it provides a secure connection of the conductors to the connectors and allows sensing or applying a field to take place.


Therefore, it would have been an obvious matter of design choice to modify Kroll (or Pless or Hoffman or Ayers or Yang or Littmann) to obtain the invention as specified in the claim(s).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703 306-4520 for regular communications and 703 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1148.

GRE
May 19, 2003


GEORGE R. EVANISKO
PRIMARY EXAMINER

5/19/3